2 courses of consolidation chemotherapy were 81.1/41.3 %, 41.4/29.7 % and 59.7/50.0 %, respectively. Major toxicities were as follows; G4 neutropenia in MVP, IC, PC were 76.9, 13.1, 4.2 % (p<.001), and G3-4 non-hematological toxicities (decrease in PS, and febrile neutropenia) were 13.3, 6.2, 4.2 % (p=.01), and 29.4, 6.9, 4.9 % (p<.001), respectively. The overall response rates were 65.7 % (95%CI 57.9-73.5), 58.6 % (95%CI 50.5-66.1) and 62.9 % (95%CI 55.0-70.8), in MVP, IC and PC, respectively. Complete analysis will be fixed in Oct 2008.

Conclusions: Weekly PC with TRT appears good compliance with high achievement rate and MVP appears poor compliance with severe hematological and non-hematological toxicities.

C3-04 Combined Modality Therapy in NSCLC II, Wed, 10:30 - 12:15

Phase III study comparing a preoperative (PRE) and a perioperative (PERI) chemotherapy (CT) with two different CT regimens in resectable stage I-II non-small cell lung cancer (NSCLC): the IFCT 0002 protocol

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Background: The association of surgery and chemotherapy is now a standard in stages IA-III. The primary objective of this trial was to define the best timing of CT (all before surgery versus perioperative). Another objective was to compare two regimens, gemcitabine-cisplatin (**GP**) and paclitaxel-carboplatin (**TC**) (GP: Gemcitabine 1250 mg/m^2/d1, 8 and cisplatin 75 mg/m^2/d1 q3 wk; TC: Paclitaxel 200 mg/m^2/d1 and carboplatin AUC 6, q3 wk).

Methods: 528 stage I-II resectable NSCLC were randomized to 4 parallel arms: A: 2 GP + in responders, 2 GP, then surgery, B: 2 GP + surgery + in responders, 2 GP, C: 2 TC cycles + in responders, 2 TC then surgery, D: 2 TC + surgery + in responders, 2 TC. Quality of life was evaluated with the EORTC QLQ C30 - LC13 questionnaire at days 1, 42 and 147. Results were analyzed two by two: **PRE** (A+C) versus **PERI** (B+D) and **GP** (A+B) versus **TC** (C+D).

Results: 1) The addition of 2 additionnal preoperative CT cycles in responders did not influence tumor volume, intratumoral necrosis, pleural, venous or intrapulmonary lymphatic invasions. Pathological complete response rates were not statistically different (PRE: 6.3%, PERI: 7.6%, GP: 8.2%, TC: 5.6%). Objective responses were similar (PRE: 50.6%, PERI: 50.9%, GP: 52.2%, TC: 49.2%) 2) 30-day postoperative mortality were identical whether the patient received 2 or 4 cycles before surgery. Similarly, iatrogenic mortality at 6 months did not differ with the number of preoperative CT cycles (PRE:3%, PERI:3.21%). The main toxicities differs betweeen GP and TC only for G ≥2 neuropathy at 6 months (GP: 6.5%, TC: 24.4%, p<10^{-3}) and G ≥2 nausea (GP: 22.17%, TC: 4.22%, p<10^{-3}) .3) Proportions of pts receiving cycles 3 and 4 were higher when they were given before surgery than after surgery (PRE: 90.4%, PERI:75.2 %, p=.0011). Percentages of non operated pts after CT were identical in both groups (PRE: 4.5%, PERI: 4.3%). 4) There was no difference in Quality of Life between the 4 groups. At 6 months, decrease of health status, different functionning and symptoms did not differ between the 4 arms in responding pts (except for alopecia).

Conclusions: 1- GP and TC were both effective and safe, although with different toxicity profiles. **2**- Results of pathological response suggested that 2 preoperative cycles might be as effective as 4 cycles. **3**- Dose intensity was higher when all chemotherapy was given before surgery compared to both before and after surgery. **4**- Quality of life decrease in the same proportions in each group within the 6 months after randomization.

C3-05 Combined Modality Therapy in NSCLC II, Wed, 10:30 - 12:15

Chemotherapy (CT) in addition to surgery or surgery plus radiotherapy (RT) in non-small cell lung cancer (NSCLC): Two meta-analyses using individual patient data (IPD) from randomised controlled trials (RCTs)

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Background: A previous IPD meta-analysis (BMJ 1995;311:899) that suggested cisplatin-based CT may have a role in the treatment of NSCLC has been updated. This includes RCTs, regimens and outcomes that were not available in 1995. The meta-analysis examines the role of CT in 7 treatment comparisons. Here we report on Comparison 1: surgery + CT versus surgery alone and Comparison 3: surgery + RT + CT versus surgery + RT.

Methods: RCTs were identified by comprehensive search strategies. Updated IPD were collected, checked and re-analysed. Results from RCTs were combined using the stratified (by trial) logrank test to calculate individual and pooled hazard ratios (HRs).

Results: Comparison 1

IPD were obtained from 30 RCTs and 8147 patients, representing 95% of all known randomised patients, adding 18 RCTs and 5835 patients to the 1995 analyses. Median follow-up is 5.3 years. 15 RCTs used a cisplatin combination without Tegafur/Tegafur+Uracil (UFT), 8 RCTs used Tegafur/UFT without cisplatin and 7 RCTs used Tegafur/UFT and cisplatin. There is a significant benefit of CT on survival (HR=0.86, 95% CI 0.81-0.93, p<0.0001), with an absolute benefit of 4% (from 60% to 64%) at 5 years. Results were similar for recurrence-free survival (HR=0.83, 95%CI 0.77-0.91, p<0.0001, 14 RCTs) local (HR=0.76, 95% CI 0.66-0.87, p<0.0001, 12 RCTs) and distant recurrence-free interval (HR=0.83, 95% CI 0.74-0.93, p=0.001, 12 RCTs).

Comparison 3

IPD were obtained from 11 RCTs and 2,626 patients (12% with incomplete resection), representing 86% of all known randomised patients, adding 5 RCTs and 1956 patients to the 1995 analysis. Median follow-up is 6.3 years. 10 RCTs used sequential radio-chemotherapy, 8 RCTs used cisplatin + vinca alkaloid/etoposide, 1 used cisplatin + Tegafur and 2 used other cisplatin regimens. There is a significant benefit of CT on overall survival (HR=0.88, 95% CI 0.80-0.96, p=0.0062), with an absolute benefit of 5% (from 29% to 34%) at 5 years. Results were similar for recurrence-free survival (HR=0.84, 0.77-0.93, p=0.0006,